29. **There were minor discrepant/incorrect statistical conclusions between what is reported in the summary text and what is shown the raw data tables. These should be rectified as part of your clinical data update. These are as follows:**

a. **In the safety summary table on p.40 (Volume 1), the rates for New Rheumatic Disease Diagnosis are reported as 0.5% and 0.4% for augmentation and reconstruction, respectively. However, the computer output which appears to have generated these rates shows them to be 0.38% for augmentation and 0% for reconstruction (Volume 2, p.712 and p.720). Please rectify this discrepancy.**

29a Response:

The numbers reported in the computer output are accurate. These numbers have been updated in Table 8.7.1 in the attached 3-Year Core Gel Study Update. As the clinical summary is not being updated, it is not submitted in this amendment.

b. **On the bottom of p.40, you stated, "Reconstruction patients who smoke were found to be at a higher risk of reoperation." This does not agree with Table 10.11 (p.1045) that shows the risk to be significantly lower. Please rectify this discrepancy.**

c. **In Table 5.4.7-A on p.98 (significant Cox findings), *Explantation with or without replacement*: The risk factor reference for augmentation should be periareolar, not inframammary. The conclusion "inframammary associated with lower risk" is not true. The risk was similar (p.1024). Please rectify these discrepancies.**

d. **In Table 5.4.7-A on p.98 (significant Cox findings), *Reoperation*: The risk factor reference for augmentation should be periareolar, not inframammary. The conclusion "inframammary associated with lower risk" is not true. The risk was 37% higher. "Other/mixed" should be 9.4 times higher, not 7 (p.1045). For reconstruction, the statement, "smokers associated with higher risk" is in error. The risk was statistically significantly lower (p.1045). Please rectify these discrepancies.**

e. **In Table 5.4.7-A on p.98 (significant Cox findings), *Any Complication or Reoperation*: The risk factor reference for augmentation should be periareolar, not inframammary. "Other/mixed" should be 5.8 times higher, not 4 (p.1052). The risk for irrigating solutions among revision patients was not reported for "steroid only" (p.1053). Please rectify these discrepancies.**

29b-e Response:

The Cox Regression discrepancies have been corrected, and are accurately reflected in Table 5.4.7-A and Tables 10.1-10 in the attached 3-Year Core Gel Clinical Study Update. Some of the significant findings of the Cox regression analyses were: younger patients, submuscular placement, implant size, and use of irrigation solutions containing antibiotics generally reduce the risk of Baker Grade III or IV capsular contracture and/or reoperation. Additionally, longer incision sizes increased the risk for any complication or reoperation in revision patients.

30. **The denominators presented for the effectiveness data are not consistent with the "Actual Included" values provided in the patient accounting tables. "Actual Included" values were supposed to include the number of patients with complete data at a given timepoint, as per our breast implant guidance document. For example, satisfaction data were provided for 495 augmentation, 184 reconstruction, and 169 revision patients. However, patient accounting data shows "Actual Included" data for 519 augmentation, 221 reconstruction, and 183 revision patients. Please rectify the discrepancies regarding the number of patients evaluated for effectiveness as compared to the number identified as "Actual Included."**

30 Response:

If a subject returned for a postoperative exam, she was included as "Actual Included," as she was seen by a study Investigator. In FDA's example above, 519 augmentation subjects were seen for a postoperative visit, and of those subjects 495 completed satisfaction data. If the patient was seen for the postoperative exam, but some data points are not collected, she is and should be counted as "Actual Included."

Similarly, 23 reconstruction patients and 183 revision patients were seen for a post-operative visit, but not all of the patients completed the satisfaction questionnaire.

31. **On Table 7, p.178, you listed the Operative Report Summaries of the three indications. For one augmentation patient, you identified the surgical approach to be a "mastectomy scar." Please explain how this patient was categorized as an augmentation patient.**

31 Response:

The surgical approach was entered on the Operative Form as "Mastectomy Scar." A subsequent data clarification form changed this to "Mastopexy scar," but the correction was not made in time for the PMA submission. The correction has now been entered into the database, and the corrected descriptor appears in the appropriate tables and summaries in the attached 3-Year Core Gel Clinical Study Update.